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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration

San Francisco District
1431 Harbor Bay Parkway
Alameda, California 94102-7070
Telephone: 510-337-6700

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Our Reference: 29-16339

March 18, 1997

Lawrence R. Chapman, President and CEO
Manna Pro Corporation
7711 Carondelet Avenue, Suite 800
St. Louis, Missouri 63105

WARNING LETTER

Dear Mr. Chapman:

An inspection of your medicated feed mill located at 2962 South Cedar Avenue, Fresno, California, during the period of January 7 through 13, 1997, by Food and Drug Administration (FDA) Investigator Thomas W. Gordon found significant deviations from Current Good Manufacturing Practice (CGMP) regulations for Medicated Feeds (Title 21, Code of Federal Regulations, Part 225). Such deviations cause medicated feeds being manufactured at this facility to be adulterated within the meaning of Section 501(a)(2)(B) of the Federal Food, Drug, and Cosmetic Act (the Act).

Our investigation found failure to maintain a drug inventory system which shows the beginning and ending quantity of drugs on hand each day; failure to make a daily comparison between the actual amount of a drug used and the theoretical drug usage; failure to date and initial the proofread label when the labels are received from the printer; failure to endorse production records in writing by a responsible person; and failure to perform scheduled assays on all manufactured feeds.

Adulterating or causing the adulteration of drugs after receipt in interstate commerce, and delivering for introduction into interstate commerce of any article in violation of Section 501 or 502, are violations of Section 301(k) of the Act.

You should take prompt action to correct these CGMP violations, and you should establish procedures whereby such violations do not recur. Failure to promptly correct these CGMP

violations may result in regulatory and/or administrative sanctions. These sanctions include, but are not limited to, seizure, injunction and/or notice of an opportunity for a hearing on a proposal to withdraw approval of your Form FDA 1900's (Medicated Feed Applications) under Section 512(m)(4)(B)(ii) of the Act and 21 CFR 514.115(c)(2).

This is not intended to be an all-inclusive list of violations. It is your responsibility to ensure that all requirements of the Act are being met.

Until the violations have been corrected and verified by the FDA, the Center for Veterinary Medicine will not approve medicated feed applications for your facility.

Within fifteen (15) days of the receipt of this letter, notify this office in writing of the specific steps you have taken to correct these violations and preclude their recurrence. If corrective action cannot be completed within fifteen working days, state the reason for the delay and the time frame within which corrections will be completed. Your response should address each discrepancy brought to your attention during the inspection and in this letter, and should include copies of any documentation demonstrating that corrections have been made. Please direct your reply to Thomas W. Gordon, Investigator, Food and Drug Administration, P.O. Box 169, Fresno, California 93707.

Sincerely yours,

Charles D. Moss Acting DD

Patricia C. Ziobro
District Director
San Francisco District

cc: R. Bruce Parker, General Manager and Vice President
Manna Pro Corporation
2962 South Cedar Avenue
Fresno, California 93725